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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,172	08/29/2005	Shinji Okano	50026/052001	2033
21559	7590	05/22/2008		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER POPA, ILEANA	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 05/22/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/532,172	Applicant(s) OKANO ET AL.	
	Examiner ILEANA POPA	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,11,14,15 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9,11,14,15 and 22-29 is/are rejected.
- 7) ☒ Claim(s) 11 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/19/2008; 02/07/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 3-8 and 16-21 have been cancelled. Claims 10, 12, and 13 have been withdrawn. Claims 22-29 are new. Claims 1, 14, and 15 have been amended.

Claims 1, 2, 9, 11, 14, 15, and 22-29 are under examination.

2. All rejections/objections pertaining to claims 17 and 19 are moot because Applicant cancelled in the response filed on 02/07/2008.

Response to Arguments

Claim Objections

3. Claim 11 remains and claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant argues that Claim 11, as amended, requires that the recited step of stimulating T cells with an antigen occurs prior to the contacting step recited in claim 9, thereby obtaining the activated T cells, i.e., the stimulating step of claim 11, as amended, produces the antigen-activated T cells recited in claim 9. Claim 11, as amended, is unambiguous, and therefore the objection to claim 11 under 37 C.F.R. § 1.75(c) should be withdrawn.

Applicant's arguments are acknowledged, however, the rejection is maintained because claims 1 and recite transfection of antigen-activated cells (i.e., the cells are

antigen-activated before contacting the cells with the virus). Therefore, claim 11 reciting a method comprising the step of stimulating the T-cells with an antigen prior of contacting the cells with the virus does not further limit the subject matter of the previous claims, which already recite this step. Same considerations apply to claim 2.

4. The objection to claims 9, 11 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is withdrawn in response to Applicant's amendments to the claims filed on 02/07/2008.

Claim Rejections - 35 USC § 101

5. The rejection of claim 14 under 35 U.S.C. 101 as directed to non-statutory subject matter, is withdrawn in response to Applicant's amendments to the claims filed on 02/07/2008.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1, 2, 9, 11, 14, and 15 under 35 U.S.C. 102(b) as being anticipate by Yu *et al.* (Genes to Cells, 1997, 2: 457-466, of record7), as evidenced by Mauri-Hellweg *et al.* (J Immunol, 1995, 155: 462-472) is withdrawn in response to Applicant's amendments to the claims filed on 02/07/2008.

New Rejections

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 9, 11, 14, 15, and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu *et al.* (Genes to Cells, 1997, 2: 457-466, of record), in view of both Mauri-Hellweg *et al.* (J Immunol, 1995, 155: 462-47, of record) and Parker *et al.* (Human Gene Therapy, 2000, 11: 2377-2387).

Yu *et al.* teach using a Sendai virus vector encoding gp120 to transduce PBMCs, wherein the PBMCs are activated with phytohemagglutinin (i.e., an antigen) before contacting the cells with the Sendai virus; it is noted that PMBCs necessarily comprise CD8⁺ T-cells and therefore, the PBMCs of Yu *et al.* must necessarily comprise activated CD8⁺-T cells (see Mauri-Hellweg *et al.*, p. 468, column 1, first full paragraph, p. 470, Fig. 7) (claims 1, 2, 9, 11, 23, and 24-26) (Abstract, p. 460, column 2 and Table 1, p. 464, column 1, last paragraph). With respect to the limitation recited in claims 15 and 27, it is noted that the phytohemagglutinin-activated PBMCs necessarily include co-existent naive CD8⁺-T cells, wherein the naïve CD8⁺-T cells are not efficiently transduced.

Yu *et al.* do not teach detecting and isolating activated and transduced T cells (claims 1, 14, 22, 28, and 29). Parker *et al.* teach transducing PBMCs followed by the isolation of CD4⁺-T and CD8⁺-T cells, wherein the isolated CD4⁺-T and CD8⁺-T cells are used in cancer therapy (Abstract, p. 2368, p. 2379). It would have been obvious to one

of skill in the art, at the time the invention was made, to modify the method of Yu et al. by isolating their transduced PBMCs according to the teachings of Parker et al., with a reasonable expectation of success. The motivation to do so is provided by Parker et al., who teach the necessity to isolate and clone transduced CD4⁺-T and CD8⁺-T cells to obtain clones with optimal effector characteristic, wherein the optimal effector characteristic are needed to achieve efficient therapy (Abstract, p. 2385, column 2, second paragraph). One of skill in the art would have been expected to have a reasonable expectation of success in doing so because the art teaches that transduced T cells can be successfully detected and isolated. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633

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